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PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| <b>TRANSMITTAL FORM</b><br><br>(to be used for all correspondence after initial filing) | Application Number   | 09/902,176             |              |
|   | Filing Date          | July 10, 2001          |              |
|   | First Named Inventor | Stefan Schreiber       |              |
|   | Art Unit             | 1634                   |              |
|   | Examiner Name        | Sally A. Sakelaris     |              |
| Total Number of Pages in This Submission  | 4+6cites             | Attorney Docket Number | 25481-P001X1 |

| ENCLOSURES (Check all that apply)   |   |   |
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| <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | Remarks   |   |
| <b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>                         |   |   |
| Firm Name   | Winstead Sechrest & Minick P.C.   |   |
| Signature   | <i>Melissa D. Schwaller</i>   |   |
| Printed name  | Melissa D. Schwaller  |   |
| Date  | February 14, 2005   | Reg. No. 46,089   |

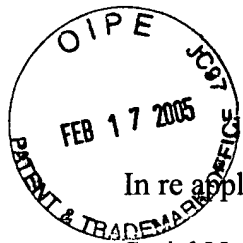
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| Signature   | <i>Viola M.L. Ange</i> |                    |
| Typed or printed name   | Viola M.L. Ange        | Date Feb. 14, 2005 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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ATTORNEY DOCKET NO.  
25481-P001X1

PATENT  
APPLICATION NO. 09/902,176



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Stefan Schreiber et al.

Serial No.: 09/902,176

Filing Date: July 10, 2001

Confirmation No: 7507

Art Unit: 1634

Examiner: Sally A. Sakelaris

Title: DIAGNOSTIC USE OF POLYMORPHISMS IN THE GENE CODING FOR THE TNF  
RECEPTOR II AND METHODS FOR DETECTING NON-RESPONDERS TO  
ANTI-TNF THERAPY

Commissioner for Patents  
P.O. Box 1450  
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Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97(b)**

Pursuant to the provisions of 37 CFR §§ 1.56, 1.97 and 1.98, and MPEP 609, Applicant submits herewith copies of the documents listed on the attached Form SB/08B "Information Disclosure Statement by Applicant."

**REMARKS**

Consideration by the Examiner of each of the documents listed on Form SB/08B is respectfully requested. Applicant respectfully requests that a copy of SB/08B, as considered and initialed by the Examiner, be returned to the undersigned with the next Official Communication.

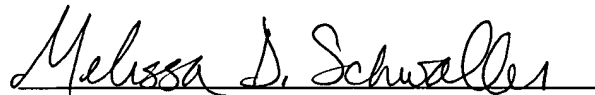
The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. 37 CFR § 1.97(g). Furthermore, the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Statement is, or is considered to be, prior art, analogous art, or material to patentability of this application, but the information has been cited to make it clear beyond all doubt that Applicant's duty of disclosure has been complied with. 37 CFR § 1.97(h).

Applicant hereby submits that the claims of Applicant's above-referenced patent application are patentably distinguishable from these references.

It is believed that no fees are due; however, the Director is hereby authorized to charge any fees relating to this Information Disclosure Statement under 37 CFR § 1.17 to Deposit Account No 23-2426 of WINSTEAD SECHREST & MINICK P.C.

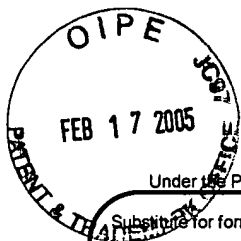
Respectfully submitted,

Date: Feb. 14, 2005

  
Melissa D. Schwaller  
Registration No. 46,089

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ATTORNEYS FOR APPLICANT



PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

|                        |                    |
|------------------------|--------------------|
| Application Number     | 09/902,176         |
| Filing Date            | July 10, 2001      |
| First Named Inventor   | Stefan Schreiber   |
| Art Unit               | 1634               |
| Examiner Name          | Sally A. Sakelaris |
| Attorney Docket Number | 25481-P001US       |

Sheet 2 of 2

**NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  | T <sup>2</sup> |
|-----------------------|--------------------------|--|----------------|
|                       |                          | ELLIOT, et al; Randomized double blind comparison of chimeric monoclonal antibody to tumor necrosis factor alpha (cA2) versus placebo in rheumatoid arthritis. Lancet 344:1105-1110, 1994.   |                |
|                       |                          | FABRIS, et al.; Tumor Necrosis Factor-alpha Receptor II Polymorphism in Patients from Southern Europe with Mild-Moderate and Severe Rheumatoid Arthritis; <a href="http://www.jrheum.com/subscribers/02/09/1847.html">http://www.jrheum.com/subscribers/02/09/1847.html</a> ; December 14, 2004  |                |
|                       |                          | OGILVIE, et al.; Treatment of psoriatic arthritis with antitumor necrosis factor-alpha antibody clears skin lesions of psoriasis resistant to treatment with methotrexate; British Journal of Dermatology 2001; 144: 587-589; UK   |                |
|                       |                          | YEE, et al.; Treatment of Complicated Sarcoidosis with Infliximab Anti-tumor Necrosis Factor-Alpha Therapy; Annals of Internal Medicine; <a href="http://www.annals.org/cgi8/content/full/135/1/27">http://www.annals.org/cgi8/content/full/135/1/27</a> ; December 14, 2004   |                |
|                       |                          | ARINGER, et al.; Safety and Efficacy of Tumor Necrosis Factor Alpha Blockade in Systemic Lupus Erythematosus; Arthritis & Rheumatism; American College of Rheumatology; Vol. 50, No. 10, October 2004; pp 3161-3169; US  |                |
|                       |                          | RUTGEERTS, et al.; Treatment of active Crohn's diseases with oncept (recombinant human soluble p55 tumour necrosis factor receptor): results of a randomized, open-label, pilot study; Ailmentary Pharmacology & Therapeutics; Volume 17, Issue 2, Page 185, January 2003; <a href="http://www.blackwell-synergy.com/links/doi/10.1046/j.1365-2036.2003.01414.x/full/">http://www.blackwell-synergy.com/links/doi/10.1046/j.1365-2036.2003.01414.x/full/</a> |                |
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|                       |                    |
|-----------------------|--------------------|
| Examiner<br>Signature | Date<br>Considered |
|-----------------------|--------------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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